

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
DAVID SHEINFELD,

Plaintiff,

vs.

B. BRAUN MEDICAL INC. & AESCULAP
INC.,

Defendants.

ANALISA TORRES, District Judge:

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23 Civ. 1622 (AT) (VF)

**ORDER ADOPTING
REPORT AND
RECOMMENDATION**

Plaintiff *pro se*, David Sheinfeld, brought this products liability action in connection with an artificial disc replacement device (the “activL Device”). *See generally* Compl., ECF No. 1. Defendants, B. Braun Medical Inc. and Aesculap Inc. (collectively, “Defendants”), moved to dismiss the complaint. Def. Mot., ECF No. 9. The Court referred the motion to the Honorable Ona T. Wang, who issued a Report and Recommendation (the “First R&R”) proposing that Sheinfeld’s complaint be dismissed for failure to state a claim and that Sheinfeld be given an opportunity to move to amend the complaint. First R&R at 11–12, ECF No. 32. The Court overruled Sheinfeld’s objections and adopted the First R&R in full. ECF No. 40.

Soon after, Sheinfeld moved for leave to file an amended complaint. ECF No. 41. The Court referred the motion to the Honorable Valerie Figueredo for a report and recommendation.¹ ECF No. 42. Before the Court is Judge Figueredo’s Report and Recommendation (the “Second R&R”), which recommends that Sheinfeld’s motion for leave to file an amended complaint be denied. Second R&R at 13, ECF No. 45. Sheinfeld filed timely objections to the Second R&R. Pl. Obj., ECF No. 46; *see also* Def. Resp., ECF No. 48.

¹ This action was redesignated from Judge Wang to Judge Figueredo on March 26, 2024.

For the reasons stated below, the Court OVERRULES Sheinfeld's objections and ADOPTS the Second R&R in full.

BACKGROUND

I. Factual Background²

On November 25, 2019, Sheinfeld underwent spinal disc replacement surgery at the Hospital for Special Surgery in Manhattan. Compl. ¶ 3. During the surgery, Sheinfeld was implanted with the activL Device, an artificial disc designed and manufactured by Aesculap Inc., a subsidiary of B. Braun Medical Inc. *Id.* The activL Device is approved by the FDA. *See* ECF No. 9-2.

On February 25, 2020, Sheinfeld attended a follow-up appointment with his surgeon, who determined that the activL Device had migrated and was “no longer in a safe position.” Compl. ¶ 5. Three days later, the surgeon performed a corrective surgery to fuse the activL Device in place. *Id.* ¶ 6.

On April 14, 2020, due to a “failure of the fusion hardware,” Sheinfeld underwent a second corrective surgery with a different surgeon at Inova Fairfax Hospital in Virginia. *Id.* ¶ 7. The surgeon who performed this corrective surgery told Sheinfeld that the original migration of the activL Device “was due to a failure of the device, and not related to the performance of the surgeons or actions of [Sheinfeld] post-surgery.” *Id.*

II. Procedural Background

On February 24, 2023, Sheinfeld filed his complaint against Defendants, alleging that the migration of the activL Device was due to negligent design or negligent manufacturing. *Id.* ¶ 9.

² The Court presumes familiarity with the full factual background of this case as detailed in the First R&R, *see* First R&R at 1–2, and therefore recounts only the key facts.

Sheinfeld also alleged that Defendants failed to adequately warn consumers of the potential risks posed by the activL Device. *Id.* ¶ 10.

Defendants moved to dismiss the complaint under Federal Rules of Civil Procedure 12(b)(2) and 12(b)(6). Def. Mot. at 1. The Court referred the motion to Judge Wang, who issued the First R&R, proposing that Defendants' motion to dismiss be granted in its entirety under Rule 12(b)(6). First R&R at 10–11. Judge Wang recommended dismissal of Sheinfeld's negligent design and negligent manufacturing claims on preemption grounds.³ *Id.* at 4–7. She stated that the claims were preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), because Sheinfeld did not plausibly plead that the activL Device "violates any specific federal requirement that could be the basis for a parallel state claim." *Id.* at 7. Instead, Sheinfeld's theory of liability amounted only to a *res ipsa loquitur* "argument that, because the activL Device migrated after surgery, there must have been negligence in its manufacture or design." *Id.*

Judge Wang also recommended that Sheinfeld be given an opportunity to move to amend his negligent manufacturing claim. *Id.* at 11–12. She explained that Sheinfeld's amended complaint must allege facts to support that (1) "the specific activL Device implanted in his spine was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction;" and that (2) "the defect was the cause of his injury." *Id.*

The Court adopted the First R&R in full. ECF No. 40. On March 21, 2024, Sheinfeld moved for leave to file an amended complaint. ECF No. 41. The Court referred the motion to Judge Figueredo, who issued the Second R&R, recommending that Sheinfeld's motion be

³ Judge Wang recommended dismissal of Sheinfeld's failure to warn claim on different grounds. *See* First R&R at 8–11. That claim is not at issue here.

denied. Second R&R at 11–13. Sheinfeld filed timely objections to the Second R&R. Pl. Obj. Defendants opposed Sheinfeld’s objections. Def. Resp.

DISCUSSION

I. Legal Standard

A district court “may accept, reject, or modify, in whole or in part, the findings or recommendations made by [a] magistrate judge.” 28 U.S.C. § 636(b)(1)(C). When a party makes specific objections, the Court reviews *de novo* the portions of the R&R to which objection is made. *Id.*; Fed. R. Civ. P. 72(b)(3). But when a party does not object or when it “makes only conclusory or general objections, or simply reiterates [their] original arguments,” the Court reviews the R&R strictly for clear error. *Wallace v. Superintendent of Clinton Corr. Facility*, No. 13 Civ. 3989, 2014 WL 2854631, at *1 (S.D.N.Y. June 20, 2014) (citation omitted); *see also Oquendo v. Colvin*, No. 12 Civ. 4527, 2014 WL 4160222, at *2 (S.D.N.Y. Aug. 19, 2014). A finding is clearly erroneous if the Court is “left with the definite and firm conviction that a mistake has been committed.” *Easley v. Cromartie*, 532 U.S. 234, 242 (2001) (citation omitted).

“*Pro se* parties are generally accorded leniency when making objections.” *Pinkney v. Progressive Home Health Servs.*, No. 06 Civ. 5023, 2008 WL 2811816, at *1 (S.D.N.Y. July 21, 2008) (citation omitted). “Nonetheless, even a *pro se* party’s objections to a [r]eport and [r]ecommendation must be specific and clearly aimed at particular findings in the magistrate’s proposal, such that no party be allowed a ‘second bite at the apple’ by simply relitigating a prior argument.” *Id.* (citation omitted).

II. Sheinfeld's Objections

Sheinfeld objects to Judge Figueredo's recommendation that the Court deny his motion for leave to file an amended complaint. *See generally* Pl. Obj. He contends that the Second R&R does not acknowledge that he "is more or less proceeding" on a *res ipsa loquitur* theory. *Id.* at 1. Sheinfeld further states that if "Judge Figueredo had applied [the *res ipsa loquitur* theory] to [his] recent pleadings, in combination with the new information and legal precedent provided by [him], she should have been able to determine that the conclusory allegations were sufficient to defeat a motion to dismiss." *Id.* at 1–2.

Shenfield's objection reiterates his original argument and misstates his pleading burden at this stage. The First R&R rejected his *res ipsa loquitur* "argument that, because the activL Device migrated after surgery, there must have been negligence in his manufacture or design." First R&R at 7. The First R&R also explained that the complaint failed to allege that the activL Device "violates a[] specific federal requirement that could be the basis for a parallel state claim." *Id.* And it set forth Sheinfeld's pleading burden at the motion to dismiss stage: Sheinfeld must allege facts sufficient to support that "the specific activL Device implanted in his spine was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction." *Id.* at 12. The Court agrees with the Second R&R that Sheinfeld's new allegations only "restate those that were deemed insufficient" in the First R&R and do not fix the deficiencies identified therein. Second R&R at 7. Shenfield's objection to the Second R&R does the same.⁴

⁴ Sheinfeld also objects to the Second R&R's interpretation of a report he provided to prove causation. Pl. Obj. at 4–5. Because the Court adopts the Second R&R on the basis that Sheinfeld does not plausibly plead that the activL Device violates any specific federal requirement that could be the basis for a parallel state claim, the Court need not address this objection.

The Court has reviewed the remainder of Judge Figueredo's thorough and well-reasoned Second R&R for clear error and finds none.

CONCLUSION

For the foregoing reasons, the Court OVERRULES Sheinfeld's objections to the Second R&R and ADOPTS the Second R&R in full. For the reasons stated in the Second R&R, Sheinfeld is DENIED leave to amend his complaint. The Court certifies under 28 U.S.C. § 1915(a)(3) that any appeal from this order would not be taken in good faith, and therefore *in forma pauperis* status is denied for the purpose of an appeal. *See Coppededge v. United States*, 369 U.S. 438, 444–45 (1962).

The Clerk of Court is respectfully directed to close this case and mail a copy of this order to Plaintiff *pro se*.

SO ORDERED.

Dated: November 4, 2024
New York, New York



ANALISA TORRES
United States District Judge